

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS



4 APR 2017

MEMORANDUM FOR SGVU

ATTN: JOSHUA CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled "When Pigs Fly ..." Investigating Brain Injury in High-Altitude
 <u>Pilots</u> presented at/published to <u>A Periodical Article for Publication in the AF Surgeon
 <u>General's Newsletter</u> in accordance with MDWI 41-108, has been approved and assigned
 local file #17168.
 </u>
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigations & Research Support

Linda Steel-Goodsin

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

- 1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D;
 Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed
 Medical Research Program (CDMRP); Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
- 2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
- 3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
- 4. Attach a copy of your abstract, paper, poster and other supporting documentation.
- Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
- 6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
- 7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
- 8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
- Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
- 10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.
- 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
 - "The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"
- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
 - "The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."
- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP:
 - "The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

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6. TITLE OF MATERIAL TO BE PUBLISHED C	R PRESENTED:						
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7. FUNDING RECEIVED FOR THIS STUDY?	YES NO FUN	IDING SOURCE:		7			
8. DO YOU NEED FUNDING SUPPORT FOR I	PUBLICATION PURPOS	SES: YES NO					
9. IS THIS MATERIAL CLASSIFIED? YES	S 🖂 NO	3000000 (300000)					
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14. 59 MDW PRIMARY POINT OF CONTACT	PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)			15.	15. DUTY PHONE/PAGER NUMBER		
Calcote, Joshua C joshua.c.calcote.ctr@i	mail.mil			210-	-292-7	143	
16. AUTHORSHIP AND CO-AUTHOR(S) List i	n the order they will app	ear in the manuscript.					
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Joshua C. Calcote	Contractor	59 MDW/SGVU					
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17. IS A 502 ISG/JAC ETHICS REVIEW REQU	IRED (JER DOD 5500.0	07-R)? ☐ YES ⊠ NO					
I CERTIFY ANY HUMAN OR ANIMAL RESEAR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108 ACCURATE MANUSCRIPT FOR PUBLICATION	. I HAVE READ THE FI	NAL VERSION OF THE ATTAC					
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21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Dr. Earl Grant, Jr., GS-14, DAF			22. APPROVING AUTHORITY'S SIGNATURE GRANT.EARL.JR.1126544380		23. DATE April 04, 2017		

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS								
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TO: Clinical Research Division	24. DATE RECEIVED	25. ASSIGNED PROCESSING REQUEST FILE I	NUMBER					
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"WHEN PIGS FLY ..." INVESTIGATING BRAIN INJURY IN HIGH-ALTITUDE PILOTS



In 2006-2011, there was a three-fold increase in neurologic decompression sickness (NDCS) in high-altitude USAF U-2 pilots. These pilots were found with increased white matter hyperintensities (WMH), which are linked to decrements in processing speed, executive functioning, and general neurocognitive status. Altitude chamber monitors and U-2 pilots who had not experienced NDCS were also observed to have increased WMH injury.

SPOTLIGHT ON RESEARCH

Col Paul Sherman, MD, in his Institutional Animal Care and Use Committee (IACUC)-approved study entitled, Brain Magnetic Resonance Imaging (MRI) and Neuropathological Effects of Hypobaric Exposure to 30,000 ft. and Hyperoxemic Exposure at Sea Level in a Sus scrofa domestica Model, wanted to investigate white matter injury seen with hypobaric (low pressure) exposure in our high altitude U-2 and F/A-18 pilots and aerospace physiology altitude chamber inside-observers.



To accomplish this, his team is exposing miniature swine to varying levels of altitude and oxygen within a mock cockpit cage model where the swine are free to move around, eat, and sleep.

59 MDW CLINICAL RESEARCH DIVISION SUPPORT

The 59th Medical Wing (59 MDW) Clinical Research Division (CRD), located on Joint Base San Antonio-Lackland in Texas, provides housing

for Col Sherman's swine in an AAALACi Emeritusaccredited vivarium.



CRD Operations Branch staff have dedicated 4,280 man-hours over the last year and have provided: expert operational support as required; subject preparation and monitoring; subject enrichment, training, and conditioning; veterinary healthcare; subject transport to hypobaric chamber and "flight" housing facilities at Brooks City-Base, TX; transport to MRI facilities at Wilford Hall Ambulatory Surgical Center, JBSA-Lackland, TX; and transport to Wright-Patterson AFB, OH during each arm of the study.

CRD Laboratory Branch staff have dedicated 400 man-hours over the last year ensuring timely processing of specimens for analysis of biosamples required to monitor the healthcare of the subjects and to provide initial basic Complete Blood Count, Coagulation, and Chemistry data for the Investigators. CRD Laboratory staff also provided recommendations to ensure blood and tissue specimens are collected, processed, and stored in a manner which facilitates a variety of additional further advanced genetic and proteomic analyses. These types of analyses will include utilizing the latest, state-of-the-art, next-generation sequencing, microarray, multiplex cytokine, and digital immunoassay and may be the key to elucidating the mechanism of WMH injury.

Data analysis is ongoing and publication of study results is forthcoming. Col Sherman states of his important work to validate an animal model for hypobaric-related brain injury, "Having a viable swine model will enable continued hypobaric exposure research, which may affect several other aircrew and special operations personnel,

and allow for potential mitigation or prevention of injury in the future."